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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,776	12/19/2005	Meir Shinitzky	74127/JPW/JW	9387

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COOPER & DUNHAM, LLP
30 Rockefeller Plaza
20th Floor
NEW YORK, NY 10112

EXAMINER	
SHTERENGARTS, SAMANTHA L	
ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
02/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,776	SHINITZKY ET AL.	
	Examiner	Art Unit	
	Samantha L. Shterengarts	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-72,135-166 and 168-212* is/are pending in the application.

4a) Of the above claim(s) *49-72,135-164,169-180 and 186-212* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *165, 166, 168, 183, 184, and 185* is/are rejected.

7)☒ Claim(s) *181 and 182* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/10, 11/2/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2010 has been entered.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on August 21, 2007 and March 19, 2008 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS documents were considered. A signed copy of each form 1449 is enclosed herewith.

Status of Claims

3. Claims 49-72 and 135-166 and 168-212 are pending. Claims 49-72, 135-164, 169-180 and 186-212 are withdrawn for being drawn to a non elected invention. Claims 165, 166, 168, and 181-185 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 185 recites the limitation "therapeutic composition comprising an antigen and an adjuvant according to claim 165" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 165 is drawn to a compound of formula R1-O-C(O)-A, and does not claim a composition which can comprise any additional agents or carriers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 184 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of adjuvant arthritis and experimental autoimmune encephalomyelitis does not reasonably provide enablement for the full scope of immunologically mediated acute or chronic inflammatory diseases, disorders or conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: (a) breadth of the claims; (b) nature of the invention; (c) state of the prior art; (d) level of one of ordinary skill in the art; (e) level of predictability in the art; (f) amount of direction provided by the inventor; (g) existence of working examples; and (h) quantity of experimentation needed to make or use the invention based on the content of the disclosure. (See Ex parte Forman 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988).

The above factors, regarding the present invention, are summarized as follows:

(a) **Breadth of the claims** - The breadth of the claims is drawn to a pharmaceutical composition for the treatment of any immunologically mediated acute or chronic inflammatory disease, disorder or condition.

(b) **Nature of the invention** - The nature of the invention is therefore drawn to the

pharmaceutical art.

(c,e) **State of the prior art and predictability in the art** - The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat or prevent which specific disease by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventative regimen on its face.

While a full discussion of each disease which is encompasses by Applicant's claim language will not be given, the following examples teach that the start of the prior art with respect to the claimed disorders has not advanced to the point of being predictive of the treatment and prevention of the breadth of diseases instantly claimed.

For a compound or genus to be effective against inflammation generally is contrary to medical science. Inflammation is a process, which can take place individually in any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There is no common mechanism by which all, or even most, inflammations arise. Accordingly, treatments for inflammation can normally be tailored to the particular type of inflammation present, as there is no, and there can be no, "magic bullet" against inflammation generally. Inflammation is the reaction of vascularized tissue to local injury; it is the name given to the stereotyped ways tissues respond to noxious stimuli. These occur in two fundamentally different types. Acute inflammation is the response to recent or continuing injury. The principal features are dilation and leaking of vessels. Chronic inflammation or "late-phase inflammation" is a response to prolonged problems, orchestrated by T-helper lymphocytes. It may feature recruitment and activation of T- and B-lymphocytes, macrophages, eosinophils, and/or fibroblasts. The hallmark of chronic inflammation is infiltration of tissue with mononuclear inflammatory cells. Granulomas are seen in certain chronic inflammation situations. There are clusters of macrophages, which have stuck tightly together, typically to wall something off. Granulomas can form with foreign bodies such as aspirated food, toxocara, silicone injections, and splinters. This discussion, demonstrates the extraordinary breadth of the causes, mechanisms, and treatment (or lack thereof) for inflammation. It establishes that it is not reasonable to accept any agent for treatment and prevention of inflammation generally.

With regards to the broad scope of inflammatory autoimmune disorders as claimed, the autoimmune process can have varied consequences. For example, slow destruction of a particular type of cell or tissue, stimulation of an organ into excessive growth or interference in its functions. The broad and divergent list of diseases in the claims each have a different mode of action and mechanism for

treatment and/or prevention. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

(d) **Level of one of ordinary skill in the art** - The artisans using applicant's method would be a collaborative team of synthetic chemists and/or health practitioners, possessing commensurate degree level and/or skill in the art, as well as several years of professional experience.

The level of skill in the art is high; however, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro or in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

(f-g) **Amount of direction provided by the inventor and existence of working examples** - The only direction or guidance present in the instant specification is the listing of disorders applicant considers as treatable by the claimed. There are absolutely no working examples present for the treatment of the full scope of disorders of the claims.

Test assays and procedures are not provided in the specification and the disclosure does not provide how the in vitro data correlates to the treatment of the assorted disorders of the instant claims, specifically, the full scope of diseases as claimed.

Applicant is enabled for the treatment of adjuvant arthritis and experimental autoimmune encephalomyelitis based on the specification 13, 15, 17-18, and 20-22.

Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Furthermore, there is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases/disorders or conditions claimed herein. That a single compound can be used to treat all diseases/disorders and conditions embraced by the claim is an incredible finding for which Applicant has not provided supporting evidence. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating any or all of the diseases/disorders or conditions by administering the instant claimed compound.

(h) **Quantity of experimentation needed to make or use the invention based on the content of the disclosure** - The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases, disorders, or conditions out of all conditions would be benefited by compounds in

the instant invention would provide treatment and prevention of the full scope of disorders.

A person having ordinary skill in the art at the time the invention was made would be faced with an undue amount of experimentation to use the pharmaceutical compositions for the full scope of the claimed intended uses.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. {In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)}.

The specification fails to provide sufficient support of the broad use of the methods of administering compounds of the formula (1) in the treatment of the broad list of disorders of the claims as a result necessitating one of skill to perform an exhaustive search for which diseases can be treated or prevented by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds encompassed in the instant claims, with no assurance of success.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 165, 166, 168, 183, 184, and 185 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 6204420, Miller et al.

Miller et al teaches oleylsarcosine in col. 3, Examples, Component A.

Oleylsarcosine structure is depicted below:

```
IT    10025-06-6, Oleylsarcosine
RN    10025-06-6  CAPLUS

Double bond geometry as shown.
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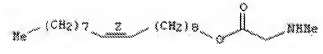
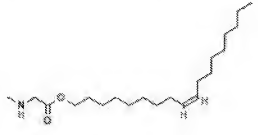


IUPAC Name: [(Z)-octadec-9-enyl] 2-(methylamino)acetate | **CAS Registry Number:** 10025-06-6
Synonyms: EINECS 233-033-6, CID6436362, 9-Octadecenyl (Z)-N-methylaminoacetate, 10025-06-6

Molecular Formula:	$C_{21}H_{41}NO_2$	Molecular Weight:	339.555740 [g/mol]



wherein in the compound of claim 165, R1-O-CO-A,

R1 is from (i) C18 alkenyl, R2 is H, R4 is H and R5 is methyl.

In claim 168, wherein R1 is trans-9-octadecenyl as shown above.

Claim Objections

7. Claims 181 and 182 are objected to for depending on a rejected base claim.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626